UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

MASON WENTZ, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. MODERNA, INC., STÉPHANE BANCEL, JAMES M. MOCK, and STEPHEN HOGE, Defendants.	**Case No.** **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff Mason Wentz ("Plaintiff"), individually and on behalf of all others similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Moderna, Inc. ("Moderna" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial, additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Moderna securities between January 18, 2023 and June 25, 2024, both dates inclusive (the "Class Period"), seeking to

recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Moderna is a biotechnology company that discovers, develops, and commercializes messenger RNA ("mRNA") therapeutics and vaccines for the treatment of infectious diseases, immuno-oncology, rare diseases, autoimmune, and cardiovascular diseases in the U.S., Europe, and internationally. The Company's products include, *inter alia*, mRESVIA (mRNA-1345), an mRNA respiratory syncytial virus ("RSV") vaccine, intended to protect adults aged 60 years and older from lower respiratory tract disease caused by RSV infection.

3. In July 2023, Moderna initiated a rolling submission of a Biologics License Application ("BLA") to the U.S. Food and Drug Administration ("FDA")—or the process by which a pharmaceutical company may submit completed sections of a BLA for review by the FDA before all sections become available—for real-time review of mRNA-1345 backed by late-stage data, which indicated a vaccine efficacy rate of 83.7% as defined by two or more RSV symptoms related to the lower respiratory tract.

4. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) mRNA-1345 was less effective than Defendants had led investors to believe; (ii) accordingly, mRNA-1345's clinical and/or commercial prospects were overstated; and (iii) as a result, the Company's public statements were materially false and misleading at all relevant times.

5. On May 31, 2024, Moderna issued a press release "announc[ing] that the [FDA] has approved mRESVIA (mRNA-1345) . . . to protect adults aged 60 years and older from lower

respiratory tract disease caused by RSV infection." However, the Company's press release indicated a vaccine efficacy of only 78.7%, significantly lower than the 83.7% vaccine efficacy that Moderna had previously identified in its mRNA-1345 BLA rolling submission to the FDA. Following this announcement, analysts and market observers were quick to note mRNA-1345's lower-than-expected efficacy rate.

6. On this news, Moderna's stock price fell $8.94 per share, or 5.9%, to close at $142.55 per share on May 31, 2024.

7. Then, on June 26, 2024, in a presentation before the Centers for Disease Control and Prevention's ("CDC") Advisory Committee on Immunization Practices, Moderna disclosed that after 18 months, mRNA-1345 proved only 49.9% to 50.3% effective against multiple symptoms of lower respiratory tract disease—a significantly lower efficacy rate than vaccines produced by Moderna's competitors.

8. Following this presentation, market analysts once again took notice of mRNA-1345's reduced efficacy rate. For example, in an article published the same day, *Reuters* stated, in relevant part, that "Moderna [. . .] opens new tab respiratory syncytial virus (RSV) shot mRESVIA showed 50% efficacy in preventing RSV after 18 months," and that, by comparison, the RSV vaccines of Moderna's competitors GSK and Pfizer were "78% effective in preventing severe RSV over a second year" and "78% effective through a second RSV season," respectively. Also on June 26, 2024, *Bloomberg* published an article entitled "Moderna RSV Vaccine Efficacy Sinks Over Time, CDC Documents Show," which stated, in relevant part, that "[t]he results could further raise doubts over the prospects for its shot, which is already third to the market. Moderna shares fell as much as 11%, their biggest intraday decline since November."

9. On this news, Moderna's stock price fell $15.15 per share, or 11.01%, to close at $122.45 per share on June 26, 2024.

10. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

11. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

13. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Moderna is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' actions took place within this Judicial District.

14. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

15. Plaintiff, as set forth in the attached Certification, acquired Moderna securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

16. Defendant Moderna is a Delaware corporation with principal executive offices located at 325 Binney Street, Cambridge, Massachusetts 02142. The Company's common stock trades in an efficient market on the Nasdaq Stock Market ("NASDAQ") under the ticker symbol "MRNA."

17. Defendant Stéphane Bancel ("Bancel") has served as Moderna's Chief Executive Officer at all relevant times.

18. Defendant James M. Mock ("Mock") has served as Moderna's Chief Financial Officer at all relevant times.

19. Defendant Stephen Hoge ("Hoge") has served as Moderna's President at all relevant times.

20. Defendants Bancel, Mock, and Hoge are collectively referred to herein as the "Individual Defendants."

21. The Individual Defendants possessed the power and authority to control the contents of Moderna's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Moderna's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Moderna, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

22. Moderna and the Individual Defendants are collectively referred to herein as "Defendants."

SUBSTANTIVE ALLEGATIONS

Background

23. Moderna is a biotechnology company that discovers, develops, and commercializes mRNA therapeutics and vaccines for the treatment of infectious diseases, immuno-oncology, rare diseases, autoimmune, and cardiovascular diseases in the U.S., Europe, and internationally. The Company's products include, *inter alia*, mRESVIA (mRNA-1345), an mRNA RSV vaccine, to protect adults aged 60 years and older from lower respiratory tract disease caused by RSV infection.

Materially False and Misleading Statements Issued During the Class Period

24. The Class Period begins on January 18, 2023, the day after Moderna issued a press release during post-market hours entitled "Moderna Announces mRNA-1345, an Investigational Respiratory Syncytial Virus (RSV) Vaccine, Has Met Primary Efficacy Endpoints in Phase 3 Trial in Older Adults." The press release stated, in relevant part:

> Moderna [. . .] today announced positive topline data from its ConquerRSV Phase 3 pivotal efficacy trial of mRNA-1345, an investigational mRNA vaccine targeting respiratory syncytial virus (RSV) in older adults. ***Following review by an independent Data and Safety Monitoring Board (DSMB), the primary efficacy endpoints have been met, including vaccine efficacy (VE) of 83.7% (95.88% CI: 66.1%, 92.2%; p<0.0001) against RSV-associated lower respiratory tract disease (RSV-LRTD) as defined by two or more symptoms***. Based on these results, Moderna intends to submit for regulatory approval in the first half of 2023.
>
> "Today's results represent an important step forward in preventing lower respiratory disease due to RSV in adults 60 years of age and older. These data are encouraging, and represent the second demonstration of positive phase 3 trial results from our mRNA infectious disease vaccine platform after, Spikevax, our COVID-19 vaccine. We look forward to publishing the full data set and sharing the results at an upcoming infectious disease medical conference," said [Defendant] Bancel[.] "Respiratory diseases are a major public health priority given they have

> a significant health impact and are a leading cause of hospitalization. For these reasons, in addition to our mRNA-1345 RSV vaccine candidate, we are committed to developing a portfolio of respiratory mRNA vaccines to target the most significant viruses causing respiratory disease, including COVID-19, influenza, and human metapneumovirus."[1]

25. On January 30, 2023, Moderna issued a press release entitled "Moderna Granted FDA Breakthrough Therapy Designation for mRNA-1345, An Investigational Respiratory Syncytial Virus (RSV) Vaccine Candidate." The press release stated, in relevant part:

> Moderna [. . .] today announced mRNA-1345, an investigational mRNA vaccine candidate for respiratory syncytial virus (RSV), has been granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration (FDA) for the prevention of RSV-associated lower respiratory tract disease (RSV-LRTD) in adults aged 60 years or older. The designation was based on positive topline data from the ConquerRSV Phase 3 pivotal efficacy trial.
>
> "The FDA's Breakthrough Designation for mRNA-1345 further emphasizes the significant health impact of RSV in older adults and the high unmet need," said [Defendant] Bancel[.] "With this designation, we look forward to productive conversations with the FDA in the hopes of bringing our RSV vaccine candidate for older adults to the market safely and quickly. Moderna's mRNA platform has now demonstrated two positive Phase 3 infectious disease trial results and we continue to advance a portfolio of respiratory mRNA vaccines targeting the most serious diseases. We are grateful to the FDA for this designation."
>
> The FDA's Breakthrough Therapy Designation is granted to expedite the development and review of drugs that are intended to treat a serious condition, and when preliminary clinical evidence indicates the drug or vaccine may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s).

26. On February 23, 2023, Moderna issued a press release announcing the Company's fiscal Q4 and full year 2022 financial results. The press release stated, in relevant part:

> "2022 was another impressive year for Moderna, with over $19 billion in revenue and significant clinical breakthroughs across our portfolio. We continue to provide our Omicron-targeting bivalent vaccines worldwide, with the latest real-world evidence highlighting the continued protection of our vaccines against hospitalization and death," said [Defendant] Bancel[.] "Our infectious disease platform continues to progress with positive Phase 3 data in RSV for older adults.

[1] All emphases included herein are added unless otherwise indicated.

> We are investing to scale Phase 3 manufacturing for personalized cancer vaccines so that we can run several Phase 3 studies simultaneously. With planned R&D investments of $4.5 billion for the year, I am excited about the new medicines we believe we will bring to patients in the coming few years."
>
> ***
>
> - ***RSV vaccine in older adults (mRNA-1345) met its primary efficacy endpoint and received Breakthrough Therapy Designation from FDA. mRNA-1345 demonstrated vaccine efficacy of 83.7% against RSV lower respiratory tract disease, defined by 2 or more symptoms, and 82.4% with 3 or more symptoms in older adults***. mRNA-1345 was generally well-tolerated, with no safety concerns identified by the Data Safety Monitoring Board (DSMB). Based on these results, Moderna expects to submit a Biologics License Application (BLA) for mRNA-1345 to the FDA in the first half of 2023. The pediatric Phase 1 trial of mRNA-1345 is fully enrolled.

27. That same day, Moderna hosted an earnings call with investors and analysts to discuss the Company's Q4 2022 results (the "Q4 2022 Earnings Call"). During the scripted portion of the Q4 2022 Earnings Call, Defendant Hoge stated, in relevant part:

> And moving to RSV, as you know, we shared the top line results from our Phase 3 RSV study in older adults earlier this year. And today, we shared additional data that was presented this morning at RSVVW. ***The top line results we have seen are incredibly encouraging and we are grateful to the FDA for breakthrough therapy designation for mRNA-1345, which further emphasizes the significant health impact of RSV in older adults and the high unmet need. In the top line data presented in January, the mRNA-1345 demonstrated 83.7% vaccine efficacy and the primary endpoint of lower respiratory tract disease with two or more symptoms***. 1345 was found to be generally well tolerated and there were no safety concerns identified by the Data and Safety Monitoring Board.

28. On February 24, 2023, Moderna filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the year ended December 31, 2022 (the "2022 10-K"). In providing an overview of the Company's strategy, the 2022 10-K stated, in relevant part:

> We believe that the development of mRNA medicines represents a significant breakthrough for patients, our industry and human health globally. Our success in developing a highly effective vaccine against COVID-19, going from sequence

selection, conducting clinical trials and to receipt of regulatory authorization for emergency use, all in less than a year, and subsequently receiving BLA approval from the FDA, provides a visible example of the promise of mRNA medicine. The Moderna COVID-19 Vaccine/Spikevax has been authorized for use or approved in over 70 countries. As our first approved product, Spikevax has helped hundreds of millions of people worldwide combat the COVID-19 pandemic. We believe our success in developing our COVID-19 vaccines has positive implications beyond infectious disease vaccines and across our entire pipeline. We currently have 48 programs in development, and our pipeline spans infectious diseases, including vaccines against respiratory diseases, latent diseases and public health pathogens, as well as four therapeutic areas: immuno-oncology, rare diseases, cardiovascular diseases and autoimmune diseases.

In order to deliver on the full scope of the mRNA opportunity and maximize long-term value for patients and investors, we have formulated strategic priorities that guide our near-term and long-term goals:

1. **Execute our commercialization plans for our COVID-19 vaccines**. Our COVID-19 vaccines have been approved in more than 70 countries. We are transitioning to prepare for an endemic, commercial market for COVID-19 vaccines in the United States and other countries. We are working to build a differentiated commercial model, with active commercial subsidiaries across North America, Europe and the Asia-Pacific region, providing us with local commercial teams in key markets around the world.

2. **Build an unrivaled seasonal respiratory vaccine franchise**. As we build our respiratory franchise, we are applying our experience and using our mRNA platform to develop medicines that can help prevent hospitalizations and deaths from the most prevalent respiratory viruses. We are currently developing vaccines against COVID-19, seasonal flu and RSV individually, while pursuing parallel development of combination vaccines. In January 2023, we announced that our older adult RSV vaccine candidate had met its primary efficacy endpoints in a Phase 3 trial. Our long-term vision is to develop, and seek regulatory approval for, a convenient, annual, single-dose booster against as many respiratory viruses as possible. mRNA vaccines have the ability to combine multiple different antigens into one vaccine. We believe that combination vaccines have the potential to improve health outcomes at lower costs due to higher compliance, better uptake, a larger benefit to the healthcare system (including through reduced vaccine administration costs) and increased consumer convenience. We have preparations underway for multiple potential vaccine launches globally over the next several years.

29. Further, in providing an overview of mRNA-1345, the 2022 10-K stated, in relevant part:

We are developing an RSV vaccine for children and adults. In older adults, mRNA-1345 reported positive topline Phase 3 efficacy results in January 2023; in pediatrics, mRNA-1345 is ongoing in a Phase 1 study.

***

mRNA-1345 encodes an engineered form of the RSV F protein stabilized in the prefusion conformation and is formulated in our proprietary LNP. We believe that neutralizing antibodies elicited by mRNA-1345 may lead to an efficacious RSV vaccine.

Latest data and next steps

In January 2023, we announced that mRNA-1345 had met primary efficacy endpoints in the pivotal Phase 3 trial in older adults, ages 60 and older. mRNA-1345 demonstrated vaccine efficacy (VE) of 83.7% (95.88% CI: 66.1%, 92.2%; p<0.0001) against RSV-associated lower respiratory tract disease (RSV-LRTD) as defined by two or more symptoms. The other primary efficacy endpoint against RSV-LRTD defined by three or more symptoms was also met, with a VE of 82.4% (96.36% CI: 34.8%, 95.3%; p=0.0078). mRNA-1345 was generally well-tolerated with no safety concerns identified by the DSMB. The overall rate of severe (Grade 3 or greater) solicited systemic adverse reactions was 4.0% for mRNA-1345 and 2.8% for placebo. The overall rate of Grade 3 or greater solicited local adverse reactions was 3.2% for mRNA-1345 and 1.7% for placebo. The study is ongoing, and an updated analysis of safety and tolerability will be provided at the time of regulatory submission.

Based on the positive topline data from the pivotal Phase 3 efficacy trial, the FDA granted mRNA-1345 Breakthrough Therapy Designation for the prevention of RSV-LRTD in adults 60 years or older. We intend to submit mRNA-1345 to the FDA for regulatory approval for older adults in the first half of 2023.

30. Appended to the 2022 10-K as exhibits were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by Defendants Bancel and Mock, attesting that "the information contained in the [2022 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company."

31. On April 11, 2023, the Company issued a press release entitled "Moderna Announces Clinical and Program Updates at 4th Vaccines Day." The press release stated, in relevant part:

mRNA-1345

mRNA-1345, Moderna's RSV vaccine candidate, is in an ongoing Phase 2/3, randomized, observer-blind, placebo-controlled case-driven trial (ConquerRSV) in adults aged 60 years and older. In this study, 35,541 participants from 22 countries were randomized 1:1 to receive one dose of mRNA-1345 or placebo.

Following review by an independent Data and Safety Monitoring Board (DSMB), the primary efficacy endpoints have been met, ***including vaccine efficacy (VE) of 83.7%*** (95.88% CI: 66.1%, 92.2%; p<0.0001) against RSV-associated lower respiratory tract disease (RSV-LRTD) as defined by two or more symptoms. Vaccine efficacy was maintained in participants over 70 years of age and participants with comorbidities. mRNA-1345 was well tolerated; solicited adverse reactions were mostly grade 1 or grade 2 in severity. No cases of Guillain-Barre Syndrome (GBS) have been reported.

mRNA-1345 has been granted Breakthrough Therapy Designation (BTD) by the FDA for the prevention of RSV-LRTD in adults aged 60 years or older.

32. On May 4, 2023, Moderna hosted an earnings call with investors and analysts to discuss the Company's Q1 2023 results (the "Q1 2023 Earnings Call"). During the scripted portion of the Q1 2023 Earnings Call, Defendant Hoge stated, in relevant part:

Moving to RSV, we're pleased by the profile of our vaccine in older adults with high and consistent efficacy against RSV lower respiratory tract disease across populations in our large Phase 3 study.

At two recent medical meetings, we've shared data showing our vaccine's efficacy was consistently high across all age groups, including in the oldest adult and in participants with preexisting comorbidities that put them at higher risk. mRNA-1345 has also shown a favorable tolerability profile with AEs mostly grade 1 or grade 2, mild to moderate. As we shared during Vaccines Day, today, we have not seen any cases of Guillain-Barré syndrome or other severe demyelinating events in the trial.

33. On July 5, 2023, the Company issued a press release entitled "Moderna Announces Global Regulatory Submissions For Its Respiratory Syncytial Virus (RSV) Vaccine, MRNA-1345." The press release stated, in relevant part:

"We are proud to announce these filings for the use of our RSV vaccine candidate, mRNA-1345, in the European Union, Switzerland, Australia, and the U.S. RSV is a major cause of lower respiratory tract infections in older adults and can cause a

> significant burden to health systems through hospitalizations and emergency care admissions," said [Defendant] Bancel[.] "Our mRNA platform has allowed us to move from initial clinical testing to our first international Phase 3 trial to initiation of regulatory submissions for mRNA-1345 in just two years, enabling us to tackle this pervasive public health burden with speed and clinical rigor. mRNA-1345 represents the second product coming from our mRNA platform to seek global approval, and with recent positive data in rare disease and cancer, we expect more in the future - further demonstrating the tremendous potential of mRNA to combat disease."

Further, the press release reiterated that "mRNA-1345 met primary efficacy endpoints, demonstrating vaccine efficacy of ***83.7%*** against RSV lower respiratory tract disease in older adults in the Phase 3 pivotal efficacy trial[.]"

34. On August 3, 2023, Moderna issued a press release announcing the Company's Q2 2023 financial results. The press release stated, in relevant part:

> "Second quarter sales were on target, given the seasonal nature of Covid. I am pleased with the progress our U.S. commercial team has made to get new contracts in place for fall 2023. We are on track to deliver 2023 sales between $6 billion to $8 billion, depending on Covid vaccination rates in the U.S.," said [Defendant] Bancel[.] "Our late-stage clinical pipeline is firing on all cylinders with four infectious disease vaccines in Phase 3, including RSV which was recently submitted to regulators for approval. Our individualized neoantigen therapy is now in Phase 3 for melanoma and our lead rare disease program for PA is in dose confirmation. We believe that all these products should launch in 2024, 2025 or 2026, and we are continuing to invest in scaling Moderna to bring forward an unprecedented number of innovative mRNA medicines for patients."

35. That same day, Moderna hosted an earnings call with investors and analysts to discuss the Company's Q2 2023 results (the "Q2 2023 Earnings Call"). During the scripted portion of the Q2 2023 Earnings Call, Defendant Bancel stated, in relevant part "[w]e've also started to manufacture mRNA-1345 in preparation for the launch. As a reminder, at launch, these products will be in a prefilled syringe presentation, ***which combined with the strong efficacy profile will position very well our product to healthcare professionals***."

36. Also during the scripted portion of the Q2 2023 Earnings Call, Defendant Hoge stated, in relevant part:

> Moving to RSV. As [Defendant Bancel] mentioned earlier, we are pleased to be on track for regulatory approvals in 2024. Earlier this month, we announced a rolling submission to the FDA, and we plan to use a priority voucher to accelerate that review. We also filed additional regulatory applications in Europe, Switzerland, Australia, and the UK. ***We're incredibly encouraged by the profile of mRNA-1345 and look forward to the expected commercial launch next year***.

37. On September 13, 2023, the Company issued a press release entitled "Moderna Expands the Field of mRNA Medicine with Positive Clinical Results Across Cancer, Rare Disease, and Infectious Disease." The press release stated, in relevant part:

> **Expanding the Field of mRNA Medicine**
> Moderna was founded and built to use nature's information molecule, mRNA, to treat and prevent disease. The premise has always been that an mRNA-based approach to making medicine could advance at the pace of information, leveraging common science, technology, and infrastructure to create medicines addressing high unmet needs at unprecedented speed and efficiency.
>
> Through more than a decade of investment in science, the Company has created the field of mRNA medicine. The Company has advanced a diverse pipeline and demonstrated the potential for clinical benefit in cancer (mRNA-4157), in three different rare diseases (mRNA-3705, mRNA-3927, mRNA-3745), and multiple infectious disease vaccines (mRNA-1273, ***mRNA-1345***, mRNA-1010). The Company has advanced six programs into late-stage development, including two approved or filed for approval, and three more that have completed Phase 3 enrollment. The Company expects to double the number of programs in Phase 3 by 2025 and launch up to 15 products in five years across cancer, rare disease, and infectious disease. Up to four of those launches could come by 2025.

Further, the press release reiterated that mRNA-1345 "met both its primary efficacy endpoints, with a vaccine efficacy (VE) of ***83.7%***[.]"

38. On November 2, 2023, Moderna issued a press release announcing the Company's Q3 2023 financial results. The press release reiterated that mRNA-1345 "met both its primary efficacy endpoints, with a vaccine efficacy (VE) of ***83.7%***" and stated, in relevant part:

> ***Moderna is preparing for the marketing launch of mRNA-1345 and believes its U.S. COVID-19 market share to date demonstrates the Company's ability to compete in the commercial market***. The Company is encouraged by early indications of strong consumer awareness and demand in the RSV market. Moderna believes that clinical data for its RSV vaccine supports a best-in-class profile and that its ready-to-use pre-filled syringes (PFS) offer another competitive differentiator over currently licensed products, which require multiple preparatory steps by pharmacists and clinicians. Feedback from clinicians and customers in the COVID-19 market, where Moderna has a similar presentation, validates the benefits of PFS administration. The Company's pre-launch activities at this time are largely focused on scientific exchanges and public health engagements.

39. On December 14, 2023, the Company issued a press release entitled "Moderna Announces New England Journal of Medicine Publication of Pivotal Phase 3 Clinical Safety and Efficacy Data For MRNA-1345, The Company's Investigational Respiratory Syncytial Virus (RSV) Vaccine." The press release stated, in relevant part:

> RSV is a highly contagious virus that causes severe disease across the age spectrum, including older adults. Each year in the U.S., RSV leads to approximately 60,000-160,000 hospitalizations and 6,000-10,000 deaths among older adults. Applications for mRNA-1345 have been submitted to regulators around the world. Moderna is actively preparing for an expected 2024 marketing launch of mRNA-1345 and believes its U.S. COVID-19 market share to date demonstrates the Company's ability to compete in the commercial market. If approved, mRNA-1345 would have a potential best-in-class profile and be the only ready-to-use RSV vaccine available in single-dose prefilled syringes.

40. On February 22, 2024, Moderna issued a press release announcing the Company's Q4 and full year 2023 results which reiterated that mRNA-1345 "met both its primary efficacy endpoints, with a vaccine efficacy (VE) of ***83.7%***[.]"

41. That same day, Moderna hosted an earnings call with investors and analysts to discuss the Company's Q4 2023 results (the "Q4 2023 Earnings Call"). During the scripted portion of the Q4 2023 Earnings Call, Defendant Hoge stated, in relevant part:

> Moving to our RSV vaccine candidates, we are very excited about launching the RSV vaccine this year. That will be the launch of our second product. Our mRNA platform is delivering. The FDA PDUFA date is May 12. If the outcome is positive, we anticipate that ACIP will include mRNA-1345 on the agenda in late June.

***

> Let me now turn to our RSV vaccine profile. ***We believe we have the best profile to serve patients and completing the RSV market, efficacy, safety, and ease of use. Our clinical data shows strong vaccine efficacy***. We have a well-established safety and tolerability profile that leverages the same mRNA technology that has been delivered in over 1 billion COVID vaccines. Additionally, we have not seen any case of Guillain-Barre Syndrome or GBS in our Phase 3 trials.

42. On February 23, 2024, Moderna filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2023 (the "2023 10-K"). The 2023 10-K contained substantively similar descriptions of the Company's strategy and overview of mRNA-1345 as discussed, *supra*, in ¶¶ 28-29.

43. Appended to the 2023 10-K as exhibits were signed certifications pursuant to SOX by Defendants Bancel and Mock, attesting that "the information contained in the [2023 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company."

44. On March 27, 2024, the Company issued a press release entitled "Moderna Advances Multiple Vaccine Programs to Late-Stage Clinical Trials" which reiterated that mRNA-1345 "met both its primary efficacy endpoints, with a vaccine efficacy (VE) of ***83.7%***[.]"

45. The statements referenced in ¶¶ 24-44 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) mRNA-1345 was less effective than Defendants had led investors to believe; (ii) accordingly, mRNA-1345's clinical and/or commercial prospects were overstated; and (iii) as a result, the Company's public statements were materially false and misleading at all relevant times.

The Truth Emerges

46. On May 31, 2024, Moderna issued a press release "announc[ing] that the [FDA] has approved mRESVIA (mRNA-1345) . . . to protect adults aged 60 years and older from lower respiratory tract disease caused by RSV infection." However, the Company's press release indicated a vaccine efficacy of only 78.7%, significantly lower than the 83.7% vaccine efficacy rate that Moderna had previously identified in its July 2023 BLA rolling submission to the FDA.

47. Following this announcement, market analysts took notice of mRNA-1345's lower-than-expected vaccine efficacy rate. For example, *Reuters* published an article that same day entitled "US FDA approves Moderna's RSV vaccine with lower-than-expected efficacy in its label," which stated, in relevant part:

> The U.S. Food and Drug Administration approved Moderna's (MRNA.O), opens new tab respiratory syncytial virus (RSV) vaccine, the company announced on Friday, giving it a shot at much-needed new revenue from a second product.
>
> Moderna's vaccine was approved for the prevention of RSV-associated lower respiratory tract disease in adults aged 60 or older, ***but with a label indicating the shot was 79% effective at preventing at least two symptoms of RSV, such as cough and fever***.
>
> Moderna had filed for FDA approval in July on data from a late-stage trial that showed its vaccine was 84% effective at preventing those symptoms, and its shares were down more than 6% in afternoon trading.

48. On this news, Moderna's stock price fell $8.94 per share, or 5.9%, to close at $142.55 per share on May 31, 2024.

49. Then, on June 26, 2024, in a presentation before the CDC's Advisory Committee on Immunization Practices, Moderna disclosed that after 18 months, mRNA-1345 proved only 49.9% to 50.3% effective against multiple symptoms of lower respiratory tract disease—a significantly lower efficacy rate than vaccines produced by Moderna's competitors.

50. Following this presentation, market analysts once again took notice of mRNA-1345's reduced efficacy rate. For example, in an article entitled "Moderna says its RSV shot is 50% effective across a second season," *Reuters* stated, in relevant part:

> Moderna [. . .] opens new tab respiratory syncytial virus (RSV) shot mRESVIA showed 50% efficacy in preventing RSV after 18 months, the drugmaker said on Wednesday.
>
> In their clinical trials, GSK's RSV vaccine Arexvy was 78% effective in preventing severe RSV over a second year and Pfizer's was 78% effective through a second RSV season.
>
> Moderna presented the data at a meeting of the U.S. Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices. The drugmaker has previously cautioned against comparing its vaccine to rivals, noting that the trials were not head-to-head and used different case definitions for RSV disease.

51. In addition, *Bloomberg* published an article entitled "Moderna RSV Vaccine Efficacy Sinks Over Time, CDC Documents Show," which stated, in relevant part:

> Moderna [. . .] shares sank after new data showed the efficacy of its RSV shot fell sharply in the second year and was lower than that of rival vaccines.
>
> The results could further raise doubts over the prospects for its shot, which is already third to the market. Moderna shares fell as much as 11%, their biggest intraday decline since November.
>
> Moderna's shot dropped from 55% efficacy over the first 12 months to 36% in the second year in patients with at least three "lower respiratory" symptoms of RSV, according to documents posted Wednesday on the Centers for Disease Control and Prevention website.
>
> ***
>
> Jefferies analyst Michael Yee said in a research note that Moderna's new figures were "on the lower end of expectations," while pointing out that comparisons were difficult because the companies studied their vaccines during different seasons.

52. On this news, Moderna's stock price fell $15.15 per share, or 11.01%, to close at $122.45 per share on June 26, 2024.

53. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

SCIENTER ALLEGATIONS

54. During the Class Period, Defendants had both the motive and opportunity to commit fraud. They also had actual knowledge of the misleading nature of the statements they made, or acted in reckless disregard of the true information known to them at the time. In so doing, Defendants participated in a scheme to defraud and committed acts, practices, and participated in a course of business that operated as a fraud or deceit on purchasers of the Company's securities during the Class Period.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

55. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Moderna securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

56. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Moderna securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may

be identified from records maintained by Moderna or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

57. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

58. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

59. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Moderna;
- whether the Individual Defendants caused Moderna to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Moderna securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

60. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the

damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

61. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Moderna securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold Moderna securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

62. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

63. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

64. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

65. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

66. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Moderna securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Moderna securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

67. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to inModerna the market for Moderna securities. Such reports, filings, releases and statements were

materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Moderna's finances and business prospects.

68. By virtue of their positions at Moderna, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

69. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Moderna, the Individual Defendants had knowledge of the details of Moderna's internal affairs.

70. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Moderna. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Moderna's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Moderna securities was artificially inflated throughout the Class Period. In

ignorance of the adverse facts concerning Moderna's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Moderna securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

71. During the Class Period, Moderna securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Moderna securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Moderna securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Moderna securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

72. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

73. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure

that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

74. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

75. During the Class Period, the Individual Defendants participated in the operation and management of Moderna, and conducted and participated, directly and indirectly, in the conduct of Moderna's business affairs. Because of their senior positions, they knew the adverse non-public information about Moderna's misstatement of income and expenses and false financial statements.

76. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Moderna's financial condition and results of operations, and to correct promptly any public statements issued by Moderna which had become materially false or misleading.

77. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Moderna disseminated in the marketplace during the Class Period concerning Moderna's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Moderna to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Moderna within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Moderna securities.

78. Each of the Individual Defendants, therefore, acted as a controlling person of Moderna. By reason of their senior management positions and/or being directors of Moderna, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Moderna to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Moderna and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

79. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Moderna.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: August 9, 2024